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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,317	08/16/2001	Alan P. Carpenter JR.	PH-7103	4231
23914	7590	08/25/2003		
STEPHEN B. DAVIS BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			EXAMINER	
			HARTLEY, MICHAEL G	
			ART UNIT	PAPER NUMBER
			1616	
			DATE MAILED: 08/25/2003	
			14	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,317

Applicant(s)

CARPENTER ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 June 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23,25-54 and 69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-23,25-32,34-44,46-54 and 69 is/are rejected.
- 7) Claim(s) 33 and 45 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12</u> . | 6) <input type="checkbox"/> Other: _____ . |

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Response to Amendment

The amendment filed 6/30/2003 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23, 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These dependent claims recite size limitations for the liposomes that are not within the scope of the limitation in the base claim. For example, 10 nm as in claim 23 is not within the lower range of 20 nm of claim 1. Also, 10um and 4um of claims 35 and 36 are not within the upper limit of 200nm of claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6,8-14,19-23, 25-27, 29, 30, 34-41, 43, 33,46-54 and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Schneider (US 6,258,378) as supported by (EP 496,813, which is incorporated by reference in the '378 patent).

Schneider discloses a formulation comprising a gas-filled microsphere having at least one lipid or surfactant absorbed on the surface thereof and liquid-filled liposomes attached to said lipid or surfactant, see abstract, column 2, lines 16-45 and column 5, lines 45-56. Schneider discloses that the liposomes

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may be those as disclosed by WO 91/05545 (which is incorporated by reference), see column 6, lines 11-19. The liposomes disclosed by '545 have a size range of 0.07-.15 microns, which is directly within the range as claimed. Also, the gas-filled microspheres are within the claimed range, see column 4, lines 52-61. Schneider also teaches the use of the same gases as claimed, e.g., perfluorocarbons, noble gases, etc., see column 5, lines 31-39. Further, Schneider also teaches the use of some of the same lipids, surfactants, etc., as claimed, see column 4-6. The microspheres may further include be targeted to specific sites, see column 8, lines 26+. The compositions are used for methods of imaging, including MRI, ultrasound, etc. and/or for drug delivery of various drugs which are in the liposomes, see column 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23, 25-32, 34-44, 46-54 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider (US 6,258,378) in view of Unger (WO 9930620, US 6123,923 used as a US equivalent).

Schneider discloses a formulation comprising a gas-filled microsphere having at least one lipid or surfactant absorbed on the surface thereof and liquid-filled liposomes attached to said lipid or surfactant, as set forth above.

Schneider fails to specifically disclose the use of all the same surfactants, gases (e.g., perfluoroethers), targeting moieties and drugs (e.g., doxorubicin, etc.), in combination with, the specific size range of the liposomes, as set forth in the instant claims.

However, the use of such surfactants, gases, targeting moieties, drugs, size range of liposomes are well known as equivalent embodiments in analogous compositions, as shown by Unger.

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Unger teaches compositions for imaging and/or drug delivery that comprise liposomes. Unger teaches that various surfactants, gases (e.g., perfluorocarbons, perfluoroethers, etc.), drugs (e.g., doxorubicin), targeting moieties, etc., such as, those claimed, may be used as equivalents in imaging and/or drug delivery liposomes, see columns 24, 39 and 46-52. Unger also teaches that the liposomes may be in the size range of 30 to 100nm which clearly encompasses the claimed range.

It would have been obvious to one of ordinary skill in the art to substitute the surfactants, gases, drugs, etc. as claimed for those taught for use in the formulations disclosed by Schneider because such components are well known to be interchangeable equivalents to the corresponding components taught by Schneider as shown by Unger. One of ordinary skill in the art would have been motivated to employ various known equivalents, since the art as a whole in this field clearly teaches that various surfactants, gases, drugs, targeting moieties, etc. are routinely used interchangeably to optimize the vesicles formulations employed in such diagnostic and/or drug delivery formulations, as shown by both Schneider and Unger. Further, one of ordinary skill in the art would have been motivated to use liposomes having the size range as claimed in the invention of Schneider because liposomes are often within this claimed range, as taught by Unger, and Schneider teaches that any liposomes prepared from any known technique may be employed. For example, Schneider teaches the general use of liposomes, which are commonly of the size as claimed (e.g., see Unger) and fails to specify that any size range which is outside the common knowledge of the art is required.

Conclusion

Allowable Subject Matter

Claims 33 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest the specific targeting moieties attached to the gas microsphere liposome conjugate as claimed in these claims.

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Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 6/30/2003 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.\



Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
8/22/2003